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10/564,452	01/12/2006	Christina Ammann	112701-703	8957
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BELL, BOYD & LLOYD LLP P.O. Box 1135 CHICAGO, IL 60690				GWARTNEY, ELIZABETH A
ART UNIT		PAPER NUMBER		
1794				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/564,452	AMMANN ET AL.	
	Examiner	Art Unit	
	Elizabeth Gwartney	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-15 is/are pending in the application.
 - 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-15 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20061103</u> . | 6) <input type="checkbox"/> Other: ____ . |

DETAILED ACTION

Claim Objections

1. Claim 1 is objected to because of the following informalities: Line 2 of claim 1 recites "composition comprising a protein source of digestible carbohydrates ..." which appears to be a typographical error. Appropriate correction is required. In light of the disclosure on page 6, lines 35-36 and page 7, lines 19-20, the examiner is interpreting claim 1 as comprising both a protein source and a source of digestible carbohydrates.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 5 recites the limitation "the soluble fiber". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 6, 8-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Spivey-Krobath et al. (WO 02/39834).

Regarding claims 1-2, Spivey-Krobath et al. disclose a liquid or powdered reconstitutable nutritional composition (Abstract, p.5/L35- p.6/L3, p.8/L14-18) comprising a protein source, a source of digestible carbohydrates, and a source of dietary fiber, having an energy density of 1.6 kcal/ml and dietary fiber in an amount of 4 g. to about 50 g per 300 g of the composition (Abstract, p.3/L15-17, p.5/L5, p.10/Table 1).

Regarding claim 3, Spivey-Krobath et al. disclose all of the claim limitations as set forth above and that the source of fiber is fructo-oligosaccharides and/or inulin (i.e. soluble non-starch polysaccharide) (Abstract, p. 3/L17).

Regarding claim 6, Spivey-Krobath et al. disclose all of the claim limitations as set forth above. Given that Spivey-Krobath et al. disclose a nutritional composition identical to that presently claimed, it is clear that the composition would inherently possess the recited viscosity.

Regarding claim 8, Spivey-Krobath et al. disclose all of the claim limitations as set forth above and that the composition comprises a source of lipids (p.7/L8-14, p.10/Table 1).

Regarding claim 9, Spivey-Krobath et al. disclose all of the claim limitations as set forth above. Given that Spivey-Krobath et al. disclose a nutritional composition identical to that presently claimed, since lactose is not disclosed, it is clear that the composition would inherently be clinically free of lactose.

Regarding claims 10-12 and 14-15, Spivey-Krobath et al. disclose all of the claim limitations as set forth above. Spivey-Krobath also disclose administering an effective amount of a powdered or liquid reconstitutable nutritional composition (Abstract, p.5/L35- p.6/L3,

p.8/L14-18) comprising a protein source, a source of digestible carbohydrates, and a source of dietary fiber, having an energy density of 1.6 kcal/ml and dietary fiber in an amount of 4 g. to about 50 g per 300 g of the composition (Abstract, p.1/L7-8, p.3/L15-17, 30-32, p.5/L5, p.10/Table 1).

Regarding the intended use of the method, statements in the preamble reciting the purpose or intended use of the claimed invention which do not result in a manipulative difference between the claimed invention and the prior art do not limit the claim and do not distinguish over the prior art process. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963); *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) and cases cited therein, as it has been held that the recitation of a new intended use for an old product does not make a claim to that old product patentable. *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997). See also MPEP § 2111.02 and § 2112 - § 2112.02.

Further, given that Spivey-Krobath et al. disclose method as presently claimed, it is clear that such method would inherently improve the digest tract and bowel function of a patient, inherently enhance mucosal barrier function in a patient, inherently promote gut health or comfort in an elderly patient, inherently maintain or restore a well-balanced gut flora, and inherently enhance mucosal function in a human individual.

Regarding claim 13, Spivey-Krobath et al. disclose a method for preparing a nutritional composition comprising the steps of mixing a liquid or powdered reconstitutable nutritional composition comprising a protein source, a source of digestible carbohydrates, and a source of

dietary fiber, having an energy density of 1.6 kcal/ml and dietary fiber in an amount of 4 g. to about 50 g per 300 g of the composition (Abstract, p.1/L7-8, p.3/L15-17, 30-32 p.10/Table 1); and hydrating the components to provide a liquid mixture (see blending the required constituents - p.9/L1, see dissolved instantaneously in water to provide a beverage - p.6/L2).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spivey-Krobath et al. (WO 02/39834) in view of Brassart et al. (US 6,489,310).

Regarding claims 4-5, Spivey-Krobath et al. disclose all of the claim limitations as set forth above. While Spivey-Krobath et al. disclose a composition wherein the source of fiber comprises 70% by weight fructooligosaccharide (i.e. oligosaccharide) and 30% by weight inulin (p.10/Table 1) or a combination of fructooligosaccharide (i.e. soluble non-starch polysaccharide) and acacia gum (i.e. soluble non-starch polysaccharide) (p.5/L5-6), the reference does not explicitly disclose a source of fiber comprising the recited ratios including an insoluble non-starch polysaccharide.

Brassart et al. teach a enteral composition which contains a protein source, a lipid source, a carbohydrate source and a fiber blend (Abstract). Brassart et al. teach that the fiber blend comprises 5-30% inulin (soluble non-starch polysaccharide), 10-40% fructo-oligosaccharides (i.e. oligosaccharide) and 20-50% pea outer fiber (i.e. non-soluble polysaccharide) (C4/L40-44). Brassart et al. teach that enteral compositions containing a balance of soluble and insoluble dietary fiber are less viscous and can be used for tube feeding (C1/L66-C2/L3). Further, enteral compositions containing the right balance of soluble to insoluble fibers are more stable (C1/L66-C2/L3).

Spivey-Krobath et al. and Brassart et al. are combinable because they are concerned with the same field of endeavor, namely, nutritional compositions. It would have been obvious to one of ordinary skill in the art at the time of the invention to have included a fiber blend including

both soluble and insoluble fiber, as taught by Brassart et al, in the nutritional composition of Spivey-Krobath et al. for the purpose of producing a composition that is not too viscous for tube feeding and has increased stability.

With regards to acacia gum, given that Spivey-Krobath disclose the use of soluble fiber including inulin and acacia gum (p.5/L5-6, p.10/Table 1), it would have been obvious to one of ordinary skill in the art at the time of the invention to have used acacia gum as the soluble fiber in the fiber blend of modified Spivey-Krobath et al. because doing so would amount to nothing more than the use of a known soluble fiber source for its intended use in a known environment to accomplish entirely expected results.

11. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spivey-Krobath et al. (WO 02/39834).

Regarding claim 7, Spivey-Krobath et al. disclose all of the claim limitations as set forth above. While Spivey-Krobath et al. disclose a nutritional composition with 10.5 g protein/100 ml, the reference does not explicitly disclose 4.5-6.0 g protein/100ml. As caloric content and energy density are variables that can be modified, among others, by adjusting the protein content of the nutritional composition, the precise protein content would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed protein content cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the protein content of the nutritional composition disclosed by Spivey-Krobath et al. to obtain the desired balance between caloric content and

energy density (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

12. Claims 1-4 and 6-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brassart et al. (US 6,489,310)

Regarding claims 1-2, Brassart et al disclose a liquid or powdered and reconstitutable nutritional composition (C5/L52-60) comprising a protein, a source of digestible carbohydrates and a source of dietary fiber (Abstract) having an energy density of 0.7 -1.5 kcal/100ml (C5/L49-51) and dietary fiber in an amount of 1.2g/100ml (C7/Example 1/L23).

While Brassart et al. disclose a nutritional composition with 1.2g/100ml dietary fiber the reference fails to disclose levels in excess of 2.5g/100ml. As viscosity is a variable that can be modified, among others, by adjusting the dietary fiber in the nutritional composition, the precise amount of dietary fiber would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed content of dietary fiber cannot be considered critical.

Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the amount of dietary fiber in the nutritional composition of Brassart et al. to obtain the desired balance between product viscosity and the nutritional benefits of dietary fiber (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art,

discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Regarding claims 3-4, Brassart et al. disclose all of the claim limitations as set forth above and that the source of fiber comprises 5-30% inulin (soluble non-starch polysaccharide), 10-40% fructo-oligosaccharides (i.e. oligosaccharide) and 20-50% pea outer fiber (i.e. non-soluble polysaccharide) (C4/L40-44).

Regarding claim 6, Brassart et al. disclose all of the claim limitations as set forth above. Given that Brassart et al. disclose a nutritional composition identical to that presently claimed, it is clear that the composition would inherently possess the recited viscosity.

Regarding claim 7, Brassart et al. disclose all of the claim limitations as set forth above. While Brassart et al. disclose a nutritional composition with 3.8 g protein /100 ml, the reference does not explicitly disclose 4.5-6.0 g protein/100ml. As caloric content and energy density are variables that can be modified, among others, by adjusting the protein content of the nutritional composition, the precise protein content would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed protein content cannot be considered critical.

Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the protein content of the nutritional composition disclosed by Brassart et al. to obtain the desired balance between caloric content and energy density (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Regarding claim 8, Brassart et al. disclose all of the claim limitations as set forth above and that the composition comprises a source of lipids (Abstract, C5/L12-38).

Regarding claim 9, Brassart et al. disclose all of the claim limitations as set forth above. Given that Brassart et al. disclose a nutritional composition identical to that presently claimed, since lactose is not disclosed, it is clear that the composition would inherently be clinically free of lactose.

Regarding claims 10-12 and 14-15, Brassart et al. disclose all of the claim limitations as set forth above. Brassart also disclose administering the nutrition composition (C6/40-44, C8/Example 8/L2-5) of a liquid or powdered and reconstitutable nutritional composition (C5/L52-60) comprising a protein, a source of digestible carbohydrates and a source of dietary fiber (Abstract) having an energy density of 0.7 -1.5 kcal/100ml (C5/L49-51) and dietary fiber in an amount of 1.2 g/100ml (C7/Example 1/L23).

While Brassart et al. disclose a nutritional composition with 1.2g/100ml dietary fiber the reference fails to disclose levels in excess of 2.5g/100ml. As viscosity is a variable that can be modified, among others, by adjusting the dietary fiber in the nutritional composition, the precise amount of dietary fiber would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed content of dietary fiber cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the amount of dietary fiber in the nutritional composition of Brassart et al. to obtain the desired balance between product viscosity and the nutritional benefits of dietary fiber (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has

been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Regarding the intended use of the method, statements in the preamble reciting the purpose or intended use of the claimed invention which do not result in a manipulative difference between the claimed invention and the prior art do not limit the claim and do not distinguish over the prior art process. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963); *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) and cases cited therein, as it has been held that the recitation of a new intended use for an old product does not make a claim to that old product patentable. *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997). See also MPEP § 2111.02 and § 2112 - § 2112.02.

Regarding claim 13, Brassart et al. disclose a method for preparing a nutritional composition comprising the steps of mixing a liquid or powdered reconstitutable nutritional composition comprising a liquid or powdered and reconstitutable nutritional composition (C5/L52-60) comprising a protein, a source of digestible carbohydrates and a source of dietary fiber (Abstract) having an energy density of 0.7 -1.5 kcal/ml (C5/L49-51) and dietary fiber in an amount of 1.2 g/100ml (C7/Example 1/L23); and hydrating the components to provide a liquid mixture (C6/Example 1/L60-C7/L14).

While Brassart et al. disclose a nutritional composition with 1.2g/100ml dietary fiber the reference fails to disclose levels in excess of 2.5g/100ml. As viscosity is a variable that can be

modified, among others, by adjusting the dietary fiber in the nutritional composition, the precise amount of dietary fiber would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed content of dietary fiber cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the amount of dietary fiber in the nutritional composition of Brassart et al. to obtain the desired balance between product viscosity and the nutritional benefits of dietary fiber (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

13. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brassart et al. (US 6,489,310) as applied to claim 1 above, and further in view of Spivey-Krobath et al. (WO 02/39834).

Regarding claim 5, Brassart et al. disclose all of the claim limitations as set forth above. While Brassart et al. disclose that the source of fiber comprises 5-30% inulin (soluble non-starch polysaccharide), 10-40% fructo-oligosaccharides (i.e. oligosaccharide) and 20-50% pea outer fiber (i.e. non-soluble polysaccharide) (Abstract, C4/L40-44), the reference does not explicitly disclose that the soluble fiber is acacia gum.

Spivey-Krobath et al. teach that it was known to use a soluble fiber, including acacia gum, as part of a nutritional composition (p.5/L5). Given that acacia gum is a well known source

of soluble fiber used for nutritional compositions, since Brassart et al. disclose a soluble fiber as part of a fiber blend, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used acacia gum as the soluble fiber in the fiber blend of Brassart et al. because doing so would amount to nothing more than the use of a known soluble fiber source for its intended use in a known environment to accomplish entirely expected results.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Lai et al. (US 2003/0104033) teach a enteral formula containing a protein source, a source of carbohydrate, a source of dietary fiber, and a source of lipid. Lai et al. is cumulative of both Spivey-Krobath et al. and Brassart et al.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Gwartney whose telephone number is (571) 270-3874. The examiner can normally be reached on Monday - Thursday; 7:30AM - 5:00PM EST, working alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. G./
Examiner, Art Unit 1794

/Callie E. Shosho/
Supervisory Patent Examiner, Art Unit 1794